DMB

Display Date 12-18-02
Publication Date 12-19-02
Certifier

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[illegible]

[Docket No. 02P–0127]

Determination That PHENERGAN (Promethazine Hydrochloride Injection USP) 25 Milligrams/Milliliter, 10 Milliliters, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that PHENERGAN (promethazine hydrochloride (HCl) injection USP) 25 milligrams (mg)/milliliter (mL), 10 mL, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for promethazine HCl injection USP 25 mg/mL, 10 mL.

FOR FURTHER INFORMATION CONTACT: Nicole Mueller, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously

N-1

approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, is the subject of approved NDA 08–857 held by Wyeth Pharmaceuticals, a division of Wyeth. PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, is indicated for certain types of allergic reactions and sedation. In a citizen petition dated March 25, 2002 (Docket No. 02P–0127), submitted under § 314.161 and 21 CFR 10.30, PharmaForce, Inc., requested that the agency determine whether PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, was withdrawn from sale for reasons of safety or effectiveness. The

petitioner seeks this determination in preparation for filing an ANDA for promethazine HCl injection USP 25 mg/mL, 10 mL.

The agency has determined that Wyeth's PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, was not withdrawn from sale for reasons of safety or effectiveness. In support of this finding, we note that Wyeth continues to market PHENERGAN for injection in 25 mg/mL and 50 mg/mL, 1-mL vials. The 25 mg/mL, 10 mL product is a multidose vial consisting of the same drug as the 25 mg/mL and 50 mg/mL, 1-mL vials. Also, promethazine HCl is a widely used product that has been marketed for many decades in many dosage forms. Although one potential concern with any multidose injectable product is the possibility of accidental overdose, there is no evidence that the withdrawal from the market of PHENERGAN (promethazine HCl injection) 25 mg/mL, 10 mL, was in any way connected to accidental overdose. FDA has independently evaluated relevant literature and data for adverse event reports and has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined previously, Wyeth's PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to PHENERGAN (promethazine HCl injection USP) 25 mg/mL, 10 mL, may be approved by the agency.

Dated: 12/8/02
December 8, 2002.

Margaret M. Dotzel,
Assistant Commissioner for Policy.

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

BILLING CODE 4160–01–S